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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,599	07/07/2003	David P. Andrew	11669.0191USC1	7759

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/614,599	ANDREW ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,38,42-48,51-57,61-64,66 and 68-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *61-64,66 and 68-75* is/are allowed.

6)☒ Claim(s) *19,38,42-48 and 51-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment filed 12 February 2008 has been entered in full. Claims 19, 38, 42-48, 51-57, 61-64, 66, 68-75 are pending and under examination.

Withdrawn Objections And/Or Rejections

The rejection to claims 19, 38, 42-48, 51-57, 61-64, 66-75 under 35 U.S.C. 112, first paragraph, enablement, as set forth at pages 3-8 of the previous Office Action (29 October 2007), is *withdrawn* in view of the amendment and Applicant's arguments (12 February 2008).

The rejection to claims 19, 42-48 under 35 U.S.C. 112, first paragraph, written description, new matter, as set forth at pages 3-8 of the previous Office Action (29 October 2007), is *withdrawn* in view of the amendment (12 February 2008).

NEW CLAIMS REJECTIONS/OBJECTIONS

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 38, 42-48, 51-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method for determining the presence or absence of a nucleic acid molecule encoding a polypeptide comprising the amino acid sequence of **SEQ ID NO:6** in a sample, comprising..(claim 19) OR

a method for detecting cancer in a first mammalian subject, the method comprising: (a) determining the amount of a nucleic acid encoding a polypeptide comprising the amino acid sequence of **SEQ ID NO:6** in a sample..(claim 38)

does not reasonably provide enablement for:

a method for determining the presence or absence of a nucleic acid molecule encoding a polypeptide comprising the amino acid sequence of **SEQ ID NO:3...** OR

a method for detecting cancer in a first mammalian subject, the method comprising: (a) determining the amount of a nucleic acid encoding a polypeptide comprising the amino acid sequence of **SEQ ID NO:3...**.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The instant claims are not supported by an enabling disclosure because the specification fails to teach that a nucleic acid molecule encoding a mouse polypeptide comprising the amino acid of SEQ ID NO:3 can be used to indicate cancer in a sample or detect cancer in a mammalian subject.

The specification teaches that the invention is based upon the discovery of a nucleic acid sequence encoding a novel member of the Wnt signaling pathway. The novel member, FCTRX, encodes a S100 cytokine-like polypeptide. The specification

teaches that S100 cytokine polypeptides are calcium-binding molecules with cytokine and chemokine activity. The specification teaches that SEQ ID NO:1 is expressed at different levels in murine mammary tumors that arise spontaneously in Wnt-1 transgenic mice relative to control tissue. Mouse SEQ ID NO:1 was extended by assembly with other murine nucleic acid fragments resulting in SEQ ID NO:2 (page 6, lines 15-30 and Example 1, page 84). The polypeptide encoded by the open reading frame of SEQ ID NO:2 is SEQ ID NO:3 (page 7, lines 21-30). The specification states that mouse SEQ ID NO:1 is related to human extended sequence tag (EST) AA315020. EST AA315020 originates from human cells forming a metastatic tumor when implanted in mice (page 7, lines 31-35). EST AA315020 was extended to assemble the sequence of SEQ ID NO:5 (page 84, line 30-page 85, line 12). The polypeptide encoded by the open reading frame of SEQ ID NO:5 is SEQ ID NO:6 (page 8, lines 21-30). The specification states that a polypeptide having the amino acid sequence of SEQ ID NO:3 (mouse) or SEQ ID NO:6 (human) can be used as a marker for the clinical predictive value for metastatic tumors (page 10, lines 7-10).

Table 8 and Table 9 indicate that the clone of human SEQ ID NO:5 is very strongly expressed in several tumor derived cell lines compared with normal tissue, especially in colon, breast, ovary, stomach and pancreas tumors and cancer cell lines (see page 88, lines 1-10 and page 91, lines 1-8). The specification teaches that mouse SEQ ID NO:1 was originally identified in mammary tumors of Wnt-1 transgenic mice. ***However,*** the specification fails to teach the expression of mouse SEQ ID NO:1 in other mouse surgical tumor tissues or cancer cells. The specification provides no information

regarding a correlation between an increased level of expression of the mouse nucleic acid molecule and cancer. ***In addition***, the art fails to teach the employment of a mouse probe for the purpose of screening/diagnosing a particular cancer in other mammalian samples such as human. Pietas et al. (reference submitted by Applicant; Genomics Vol. 79/No.4:513-522, April 2002) teach the characterization of human S100A14. Pietas et al. employed human S100A14 as probe to detect variable levels of expression of the gene in different human cancer samples. Smirnov et al. (reference submitted by Applicant; Cancer Research 65: (12), June 2005) extract RNA from circulating tumor cells (CTC) of human patients to identify novel CTC associated genes. Smirnov et al. teach that CTC associated genes can be used for CTC monitoring in human peripheral blood. A mouse probe would be less specific in a human sample because it is a variant and thus would allow imperfect matches and carry the risk of obtaining false signals from unrelated DNA sequences.

The specification states that the mouse and human amino acid sequences are aligned in Figure 2 and that this alignment reveals that these two sequences are sufficiently similar such that they can be considered to be orthologs (page 9, lines 1-9). However, this assertion is not found persuasive because the purported utility is a feature of the nucleic acid ***not*** the amino acid. The purported utility is that the polynucleotide is useful in that it has a particular biological activity (i.e. increased expression of the nucleic acid molecule is indicative of a particular type of cancer). As was stated above, the specification provides no information regarding a correlation between an increase level of expression of the instant mouse nucleic acid and a

particular cancer. The Examiner does not doubt that a nucleic acid molecule encoding human polypeptide (SEQ ID NO:6) can serve as a marker for certain cancers but finds enablement of a nucleic acid molecule encoding mouse polypeptide (SEQ ID NO:3) for detecting/indicating the presence of cancer dubious.

Due to the large quantity of experimentation necessary to demonstrate a correlation between increased expression of a nucleic acid molecule encoding a polypeptide comprising SEQ ID NO:3 and specific cancers, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the contradictory state of the prior art which teaches the use of human probes to discern under or over expression of genes in human cancer samples and the unpredictability of employing a mouse nucleic acid as a probe in samples to detect specific cancer, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19, 42-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is indefinite because the preamble does not agree with the intended use. The preamble **(a method for determining the presence or absence of a nucleic acid molecule)** and the body of the claim **(wherein an increase in expression of the nucleic acid molecule as compared to normal cells of the same tissue type is indicative of cancer)** is not consistent, thus the metes and bounds of the instant claim cannot be determined.

Claim 19 is also indefinite because of the recitation, "a method for **determining the presence or absence** of the nucleic acid molecule.." and "**wherein an increase in expression of the nucleic acid molecule**..". The metes and bounds of the instant claim cannot be determined because it is unclear what is being compared to normal cells; the increase in expression of the nucleic acid molecule ***OR*** the presence or absence of a nucleic acid molecule.

Conclusion

Claims 19, 38, 42-48, 51-57 are rejected.

Claims 61-64, 66, 68-75 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

RMD
4/22/08